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In this paper, we describe our prototype of an ultrasound guidance system consisting of a probe-mounted, lockable, articulating needle guide and a user-interface that provides real-time visualization of the predicted needle trajectory overlaid on the ultrasound images. Our needle guide ensures that the complete needle is always physically in the ultrasound imaging plane. The guide consists of instrumented links that relay the predicted needle trajectory to a software system which overlays it on the real-time ultrasound image. As a result, the practitioner will no longer need to estimate what the target trajectory should be, thus leading to less redirection of the needle after It has been inserted into the body. Finally, the guide is lockable, thus providing a means to prevent the needle from deviating from its desired trajectory as it is being inserted. This feature will also assist the practitioner to free one hand so as to complete tasks that usually require a second practitioner to perform, such as ultrasound adjustments and injection of medication. Overall, the system eliminates the experience required to develop the fine hand movements and dexterity needed to successfully perform ultrasound-guided procedures. This increases efficiency, safety, quality, and reduces costs for all ultrasound guided procedures from central line placements to peripheral nerve blocks. Furthermore, with the recent development of highly portable ultrasound imaging systems, this system will enable these procedures to be more easily performed by unskilled practitioners in non-ideal situations such as the battlefield and other disaster relief areas.

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Field Operable Ultrasound Needle Guidance System

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***Abstract*—In this paper, we describe our prototype of an ultrasound guidance system consisting of a probe-mounted, lockable, articulating needle guide and a user-interface that provides real-time visualization of the predicted needle trajectory overlaid on the ultrasound images. Our needle guide ensures that the complete needle is always physically in the ultrasound imaging plane. The guide consists of instrumented links that relay the predicted needle trajectory to a software system which overlays it on the real-time ultrasound image. As a result, the practitioner will no longer need to estimate what the target trajectory should be, thus leading to less redirection of the needle after it has been inserted into the body. Finally, the guide is lockable, thus providing a means to prevent the needle from deviating from its desired trajectory as it is being inserted. This feature will also assist the practitioner to free one hand so as to complete tasks that usually require a second practitioner to perform, such as ultrasound adjustments and injection of medication. Overall, the system eliminates the experience required to develop the fine hand movements and dexterity needed to successfully perform ultrasound-guided procedures. This increases efficiency, safety, quality, and reduces costs for all ultrasound guided procedures from central line placements to peripheral nerve blocks. Furthermore, with the recent development of highly portable ultrasound imaging systems, this system will enable these procedures to be more easily performed by unskilled practitioners in non-ideal situations such as the battlefield and other disaster relief areas.**

I. Introduction

ULTRASOUND guided procedures are quickly becoming the gold standard for patient care. In current guided needle procedures, the practitioner first identifies the region of interest using an ultrasound probe. Once the desired anatomical structures are in view, the practitioner estimates a needle trajectory and insertion point. A tremendous challenge with ultrasound-guided procedures is continuous visualization of the needle during the entire procedure. The full length of the needle must be completely maintained within the 1mm wide ultrasound beam, as seen in Fig. 1. Often the needle is askew allowing only a portion of it to be visualized. The inability to properly identify the needle tip as depicted in Fig. 1 makes it dangerous to advance the needle. For example, improper needle placement has led to pneumothoraces, arterial dissections, inadequate tissue samples, and failed nerve blocks. This issue becomes even more problematic in uncooperative and obese patients. To resolve this issue, the practitioner is forced to continuously adjust the position of the ultrasound probe in an attempt to the needle and beam aligned. There is often a tradeoff between capturing an ideal image of the anatomy and visualizing the entire needle. Once the practitioner achieves adequate needle visualization, he or she uses a "freehand" technique to complete the procedure. The term "freehand" is used to describe a technique where the practitioner has complete flexibility with insertion points and approach angles to either avoid damaging important structures (such as arteries) and/or inject medication in different locations. Currently, many of these procedures are limited to more advanced practitioners mainly because of the fine motor skill needed to maintain needle imaging for safe placement [1].

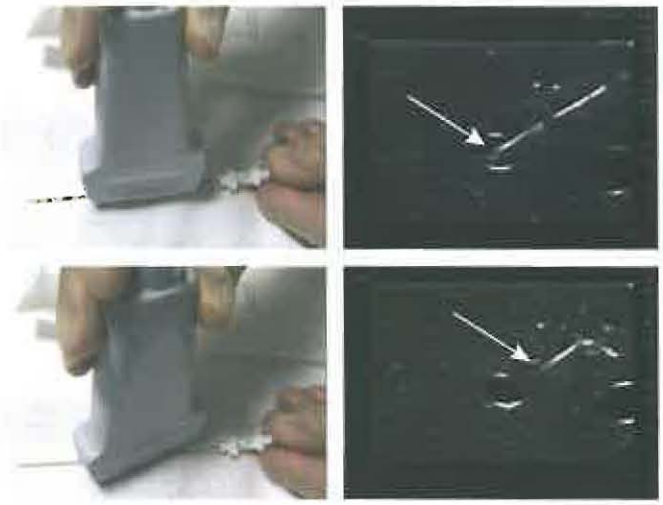

Fig. 1. Proper versus improper needle alignment. Top: Needle aligned along the 1mm wide ultrasound plane allows for full visualization including its tip indicated by arrow. Bottom: Ultrasound image reveals a "false" needle tip when not aligned.

Another issue is that these procedures commonly require two practitioners, one to insert the needle and the other to assist with ultrasound adjustments and injection of medication. With the current approach, one of the practitioner's hands is used for holding the probe while the other is used for needle placement and alignment. The requirement of a second, trained practitioner to perform simple tasks such as ultrasound adjustments adds to cost and decreases efficiency. Making ultrasound-guided procedures easier to perform can open opportunities for mid-level providers to offer cost effective care [2].

To date, no solution exists that addresses all of these issues with ultrasound-guided procedures. An ideal solution ensures that (1) the needle is precisely kept in plane with the

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ultrasound beam; (2) the needle can be rotated in this plane, allowing for one degree of freedom; (3) the needle can be translated horizontally and/or vertically, adding a second or third degree of freedom; (4) the needle can be locked in its current position; and (5) hitting the target is made easier through computer assistance. We compiled these requirements after a thorough literature and prior art search and discussions with practitioners. Most notably, the practitioners underline the importance of the aforementioned "freehand" technique that allows for undisturbed movements of the needle within the ultrasound imaging plane.

A. Prior Art

A variety of needle guides have been suggested to improve ultrasound-guided procedures. The simplest needle guides restrict the user to one entry point and a fixed angle (Fig. 2A, [3]). This limitation does not allow the practitioner to adequately adjust the needle to avoid structures such as arteries and nerves that may be in the path of the desired target – ultimately leading to significant morbidity. Wung et al. [4] designed an ultrasound needle guide allowing discrete angle alignment of the needle according to the predefined needle slits (Fig. 2B). Similarly, this needle guide does not preserve the "freehand" technique either. In an attempt to emancipate the free rotation, the needle suggested to be trapped in two parallel planes without a single-hole guidance feature (Fig. 2C, [5]). Other approaches added a translational movement to this rotation [6, 7], or focused primarily on translation to cover a large domain of insertion points [8]. Finally, Sonek [9] proposed a functional idea that allows for translational and rotational movements. Fig. 2D illustrates two joints that connect the guiding arms for needle insertion.

There are also devices that provide software to assist the needle alignment [10], as shown in Fig. 2E. Identifying the targeted feature as well as the inserting the needle is fully or semi-automated. However, these devices are often difficult to setup and use, or expensive.

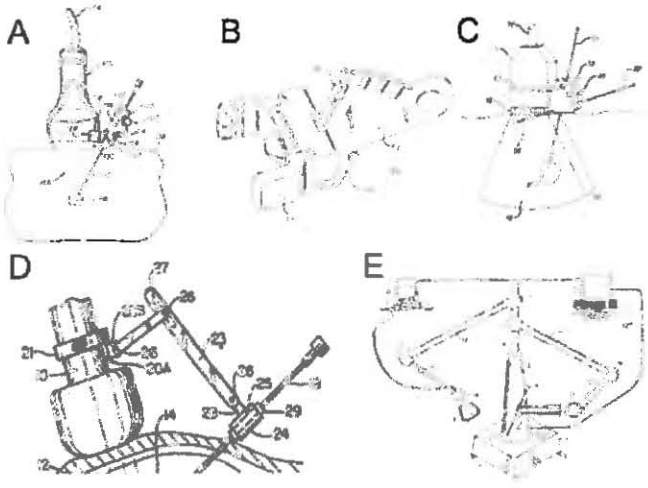

Fig. 2. Existing needle guides include small clamps attached to the ultrasound head (A, B, C), arms (D), and large, robot guided systems (E).

Complex electromagnetic (EM) tracking systems are being developed to track the position and orientation of the needle tip. Ascension Technology and Ultrasonix's SonixGPS system use an EM sensor in the ultrasound probe and another one in the needle to keep track of the needle's distal tip, enabling practitioners to access an internal target from any depth or angle, in-plane or out-of- plane [11]. The Philips PercuNav system combines electromagnetic tracking of instruments with patient images from multiple modalities to create a real-time 3D map of the patient space that displays the instrument position, orientation, and trajectory, as well as anatomical landmarks [12]. However, EM tracking is susceptible to external inferences, such as the presence of metal in the vicinity of the tracking range. In addition, a calibration process is usually required at the beginning of the procedure. The sensitivity to inference and extra steps in setting up the system make it only applicable to certain well defined conditions and less practical for procedures in general settings or battle fields.

While devices have been created to facilitate ultrasound guided procedures, no system has the ability to keep a needle in plane while simultaneously preserving the "freehand" technique (req. (1)-(3)), lock the needle in place (4), and aid with the needle insertion by a computer system (5). In this paper, we present the design of an integrated hardware and software system that is easy to use, cost effective, requires little prior training, and accomplishes all the aforementioned tasks.

II. Design Process

Previous ultrasound guidance solutions have had limited clinical adoption. Based on the patent review, medical literature, and conversations with practicing clinicians we identified the limitations in earlier approaches to understand the lack of clinical adoption. Our analysis led us to several requirements for a new needle-guidance mechanism. It must preserve the freehand technique while keeping the needle in the imaging plane. It must be lockable by the operator and provide a software interface to help guide the needle to its target. It must also be useable by one person and accommodate different needle sizes between 14 and 26 gauge.

To understand how best to implement these improvements and what secondary requirements might be needed for the needle guide, several simulated medical procedures were performed on a medical phantom. The five functional requirements are listed below in Table 1.

Table 1. The five functional requirements for the needle guide. They were realized with input from practitioners

1.	Needle is constrained to imaging plane, preserving the freehand technique within this plane.
2.	Software calculates trajectory to target using angular sensors
3.	Usable by one person

4.	Lockable relative to the ultrasound probe, freeing one of the practitioners hands to perform other tasks
5.	Different needle sizes need to be accommodated (14-26 gauge)

III. System Description

A. System Overview

We designed an ultrasound guidance system consisting of: (1) a probe-mounted, lockable, articulating needle guide and (2) a user interface that provides visualization of the projected needle trajectory overlaid on the ultrasound image. An overview of the system is provided in Fig. 2 below. The proposed ultrasound guidance system ensures that the needle is fully in the ultrasound image plane so that the practitioner always sees the needle tip. The guide consists of instrumented links that relay all three joint angles to a software system that calculates the needles projection and overlays it on the ultrasound image. Thus, the practitioner no longer needs to estimate what they feel is the desired trajectory before inserting. The guide is also lockable to hold its position once the practitioner is satisfied with the needle arrangement. This feature allows the practitioner to free one of their hands to perform tasks usually requiring a second practitioner such as ultrasound adjustments, aspiration, and injection of medication.

Fig. 2. A depiction of the system workflow: the practitioner positions the needle with the needle guide attached to the ultrasound probe and reads the desired trajectory from the ultrasound monitor before inserting the needle.

B. Mechanical Modules

The needle guide is designed to mate specifically with the Sonosite Micromaxx portable imaging system. The hardware consists of six modules: (1) Attachment, (2) Arm, (3) Needle Holder, (4) Lock, (5) Sensors, and (6) Software as illustrated in Fig. 3 (a). A diagram analyzing forces on the lock is seen in Fig. 3 (b). The needle guide design maintains the "freehand" technique by constraining the needle's motion in only *one* translational dimension and *one* rotational dimension – the minimum required the keep the needle in plane. The practitioner is free to move the needle in the remaining dimensions – up/down, forward/backward, rotation about its axis, and rotation about the Needle Holder axis. The joints are low friction, minimizing resistance to rotation while maintaining the practitioner's haptic feedback from the needle. The Arm is 10cm long when fully extended, with each joist 5cm long. The arm is completely retractable, and it can be positioned into all configurations between a full extension and a complete retraction. Each of these configurations is lockable by engaging the locking lever, allowing the practitioner to let go of the needle guide while maintain the position of the needle relative to the probe. The locking mechanism uses friction locks, allowing all the joints to lock at any position along a continuum, rather than in discrete steps. Engaging the locking lever with a force F_1 results in normal braking forces F_2 given by:

$$F_1 = 3F_2\frac{d}{D} \qquad (1)$$

Where D is the length of the lever and d is the leverage on each brake. A full diagram is seen in Fig. 3 (b). We calculate that a force, F_1, of approximately 2N is needed to engage the lock.

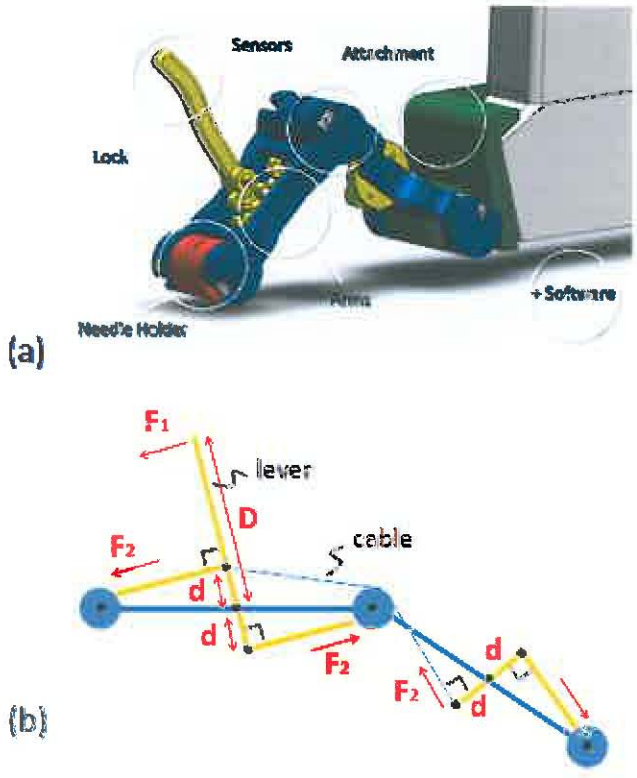

Fig. 3. **(a)** The needle guide attached to an ultrasound probe. It consists of five modules: (1) Attachment, (2) Arm, (3) Needle Holder, (4) Lock, (5) Sensors, and (6) Software. **(b)** The force diagram for the lock module. A force F_1 is applied to the lever resulting in a normal force F_2 at each of the three joints.

The guide is attached to the ultrasound probe using principles of exact constraint design so that it can be accurately and repeatedly positioned with respect to the ultrasound probe. This is important since this fixed coordinate transformation between the articulating needle guide and the imaging system will be required in order to overlay the appropriate information on the medical images.

Sensors are mounted on each of the three joints of the articulating arms to measure the rotation angles. The sensors are potentiometers which output a different voltage corresponding to a particular angle. A needle holder is attached to the end of the articulating arms that is the entry point for the needle. This needle holder is designed to accommodate the various needle sizes that are required for different procedures.

C. *Software and User Interface*

The software interface combines a live feed of the ultrasound image with a prediction of the needle's trajectory, seen in Fig. 4. The practitioner sees a red line superimposed over the image showing the needle's projected path. The path is recalculated and updated in real time, allowing the practitioner to move the needle and instantly see the updated trajectory. The interface contains a "Start" button which initiates input from the rotation sensors and displays the projected path. No further input is required from the user for the duration of the procedure. Afterwards the "Stop" button cuts input from the sensors and the needle's path stops being updated in real time. The software, the GUI, the senor inputs and the image inputs are currently implemented in MATLAB on a portable computer. The software must ultimately be integrated into an ultrasound machine to allow for greater ease-of-use. We were unable to perform this integration for lack of access to the proprietary software of commercial ultrasound systems.

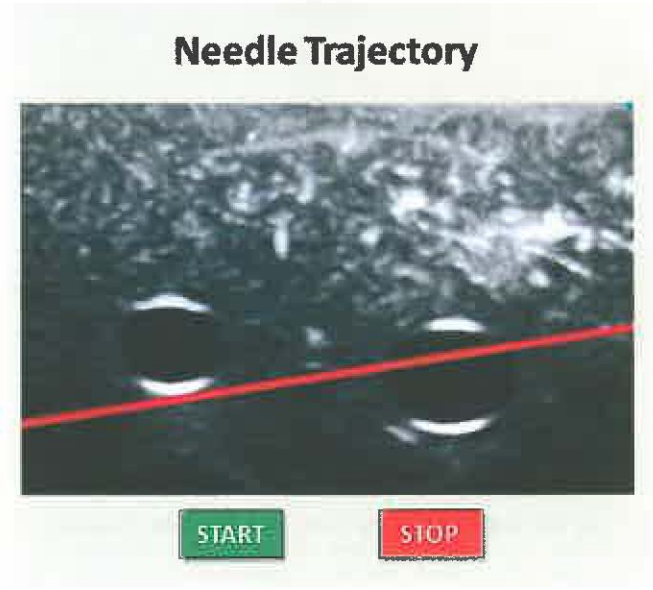

Fig. 4. The software user interface contains a live feed of the ultrasound image with a superimposed red line representing the predicted needle path. The needle path is predicted using the rotation sensors in the arm and updated in real time as the user moves the needle.

The software works by receiving data from the position sensors. There are three rotation sensors – two in the arm joints and one connecting the arm and needle holder. The position sensors used here are potentiometers that measure the angles between every two adjacent linkages of the guide. Based on a kinematic model, the position of the needle tip can then be inferred. The needle's path is predicted and superimposed over the ultrasound image showing where the needle will go with a given configuration of the guide.

The software works in real time, constantly adjusting the needle's path. This allows the practitioner to move the needle until he sees its path crossing the target on screen. Once the needle is on target, he locks the needle guide, as described above, and pushes the needle in with confidence.

The forward kinematics specifies the Cartesian position and orientation of the local frame attached to the needle guide relative to the base frame which is origin of the ultrasound image. They are derived by multiplying a series of matrices parameterized by joint angles and or translational offsets. Homogenous transformation matrices (HTM) are used in this case.

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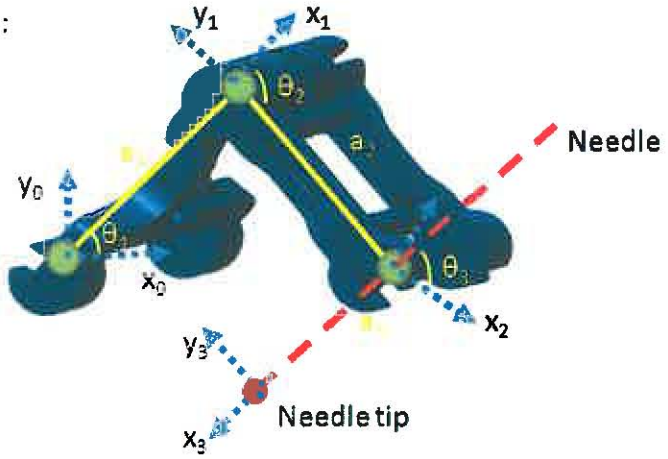


Fig. 5. The Forward Kinematic Model of the Needle Guide

Fig. 5 illustrates the forward kinematic model with the base frame chosen at the first joint, and the subsequent frames at each of the other two joints. In matrix representation, the convention is for the pre-superscript to represent the reference frame or the resultant coordinate system and the post-subscript the reference frame that is being transformed from. The following is a series of coordinate transformation matrices describing the relative position and orientation of each component from the base frame (the first resolute joint) to the needle tip.

$$A_1^0 = \begin{bmatrix} c_1 & -s_1 & 0 & a_1 c_1 \\ s_1 & c_1 & 0 & a_1 s_1 \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \quad (1)$$

$$A_2^1 = \begin{bmatrix} c_2 & -s_2 & 0 & a_2c_2 \\ s_2 & c_2 & 0 & a_2s_2 \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \quad (2)$$

$$A_3^2 = \begin{bmatrix} c_3 & -s_3 & 0 & a_3c_3 \\ s_3 & c_3 & 0 & a_3s_3 \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \quad (3)$$

$T_3^0 = A_1^0 * A_2^1 * A_{3=}^2$

$$\begin{bmatrix} c_{12}c_3 - s_{12}s_3 & -c_{12}s_3 - s_{12}c_3 & 0 & a_1c_1 + a_2c_{12} + a_3c_{123} \\ c_{12}s_3 + s_{12}c_3 & c_{12}c_3 - s_{12}s_3 & 0 & a_1s_1 + a_2s_{12} + a_3s_{123} \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \quad (4)$$

Where A_1^0 is the HTM for joint 2 (frame x_1y_1), A_2^1 is the HTM for joint 3 (frame x_2y_2), and A_3^2 is the HTM for the needle tip (frame x_3y_3).
a_i is the length of each linkage and *a prior*.
c_i is the shorthand notation for $\cos(\theta_i)$, s_i is the shorthand notation for $\sin(\theta_i)$. Both c_i and s_i are variables in the kinematic model.
Similarly, c_{12} and s_{12} are the shorthand notation for $\cos(\theta_1 + \theta_2)$ and $\sin(\theta_1 + \theta_2)$ respectively. c_{123} and s_{123} are the shorthand notation for $\cos(\theta_1 + \theta_2 + \theta_3)$ and $\sin(\theta_1 + \theta_2 + \theta_3)$ respectively.

The needle tip location (x, y) would be the first two rows in the last column of T_3^0:

$$x = a_1c_1 + a_2c_{12} + a_3c_{123}$$
$$y = a_1s_1 + a_2s_{12} + a_3s_{123} \quad (5)$$

T_3^0 is the HTM of the needle tip relatively to the base frame x_0y_0. Since only a fixed translation in x and y is needed to transform the x_0y_0 frame to the image coordinates, we pre-multiple the following HTM to T_3^0 to find the needle tip in the image coordinates:

$$T_{joint1}^{image} = \begin{bmatrix} 1 & 0 & 0 & t_x \\ 0 & 1 & 0 & t_y \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \quad (6)$$

Where t_x and t_y are the x and y offset of the x_0y_0 frame to the origin of the image frame, and they are *a prior*.

IV. Prototype Testing and Error Analysis

We conducted three sets of tests on the prototype to check how well the functional requirements in table 1 were met. The first test checked that the freehand technique was preserved. A needle was inserted and removed into a phantom several times, checking that it remained in plane each time. The second test checked that the needle was visible in the ultrasound image and aligned closely with its path as predicted by the software. The third test checked that the lock works.

In addition, we performed simulations on the accuracy of the needle trajectory prediction. The simulation results will be used as a comparison with the clinical testing in the near future.

A. Preserving the Freehand Technique

The goal of this test was to check if using our needle guide preserved the freehand technique. The practitioner first inserted the needle, then withdrew it and reinserted it at a different angle. Upon each reinsertion the practitioner risked applying lateral forces, pushing the needles out of plane. In our trials, seen in Fig. 7, the needle remained in-plane after each reinsertion. This indicates that the practitioner was able to adjust the needle's angle while the needle guide kept it aligned in the imaging plane.

Fig. 7. **(a)** The practitioner inserted a needle into a phantom under guidance from our needle guide. The needle entered into the plane of the image and is visible in the ultrasound device. Its location is marked by the red arrow. **(b)** The practitioner then pulled the needle out of the phantom and reinserted it into a different spot under. The needle remained visible in the imaging plane and is marked by the red arrow.

B. In-plane Needle Visualization

The goal of this test was to see how well the needle aligned with the ultrasound imaging plane using the needle guide and to check that the needle's path predicted by the software aligned with the actual needle. To test it, we asked the practitioners to insert the needle using the guide without making adjustments and without looking at the ultrasound screen. The needle position in the ultrasound image was

recorded for validation. Fig. 6 shows the result. Fig. 6 (a) shows the needle's predicted path before it entered the phantom. Fig. 6 (b) shows the needle being inserted into the phantom. The needle is in the imaging plane and its path corresponds closely with the predicted trajectory.

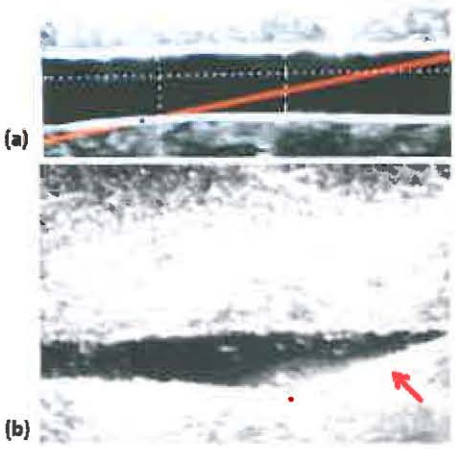


Fig. 6. (a) A projection of the needle's path before it enters the phantom. (b) A subsequent ultrasound image of the needle entering the phantom.

C. Needle Guide Lock

The goal of this test was to check that the needle stays upright when the lock is engaged. In Fig. 8 (a), before the lock was engaged, the guide fell when the practitioner let go of it. In Fig 8 (b) the practitioner engages the lock and in Fig 8 (c) the guide stays locked upright. The lock was thus successful.

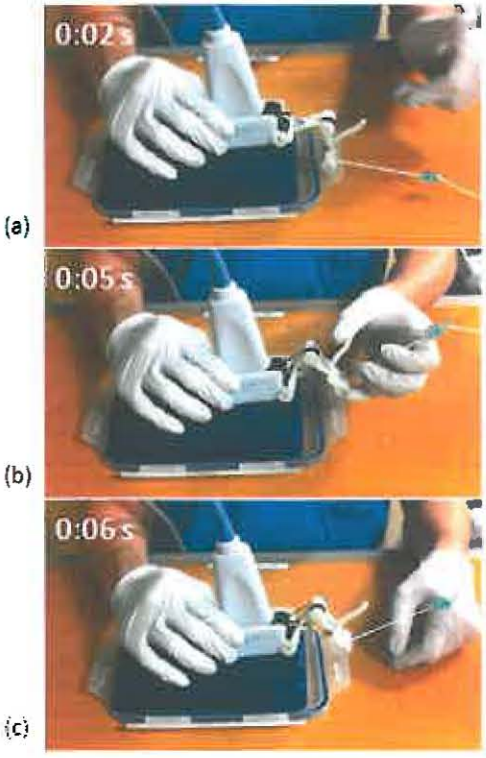


Fig. 8. A demonstration of our needle guide being locked. **(a)** The needle guide is unlocked and falls under the influence of gravity. **(b)** The practitioner is engaging the manual lock by pulling on the lever. **(c)** The lock is engaged and the needle guide stays erect when the practitioner lets go.

D. Needle Trajectory Prediction and Error Analysis

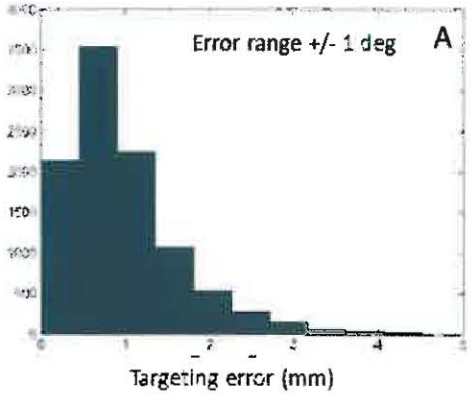
We performed needle trajectory accuracy estimation based on the kinematic model established in Equation (4) in Section III. In Equation (4), the joint angles are the variables and they are the major source of errors in the trajectory accuracy prediction.

A simulation was performed where the three sources of errors in the joint angles were all simultaneously included and a large number (~10,000) of simulations were run where each error was randomly varied between its minimum and maximum values. The configuration of the needle guide in each simulation was also randomly varied but within each joint limit. The results are shown in Table 2, which shows that if assuming an error range of +/- 1 degree, the accuracy is around 1mm, if assuming an error range of +/- 2 degree, the accuracy is between 2-3 mm.

Fig. 9 shows the histograms of the targeting errors from the 10,000 trials.

Table 2. Needle Trajectory Error Analysis

Error Range (+/- deg)	Mean (mm)	Std (mm)	RMS (mm)
1	0.95	0.65	1.15
2	2.33	1.60	2.80



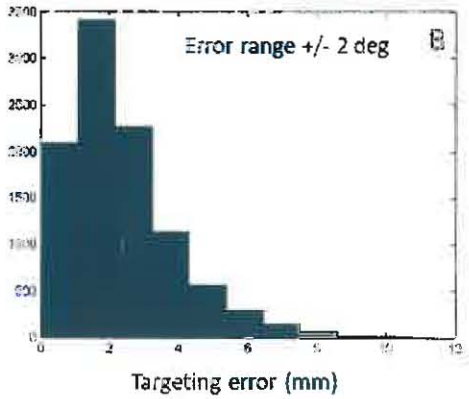


Fig. 9. Histograms of the targeting errors from the 10,000 trials including the random effects of three joint angles. (A) Error range within +/- 1 degree. (B) Error range within +/- 2 degree.

The next step is to compare the analytical error estimation with the actual clinical measurement. At the time of writing this paper, the plan for clinical testing is in progress.

We plan to perform simulated procedures on a phantom that has artificial targets that are identifiable on ultrasound imaging. Once a desired target is selected, we will use our guidance system to place a needle to a desired target. Comparisons of the trajectory images and their corresponding needle image will then be analyzed to compare accuracy of our calculations and to assess the targeting error.

V. Conclusions and Future Work

This paper presents the design of a probe-mounted ultrasound guidance system that provides increased functionality compared to existing passive needle guides at an order of magnitude less cost than commercial navigation systems. The guide consists of instrumented links that relay the predicted needle trajectory to a software system which overlays it on the real-time ultrasound image. The system will aim to decrease the experience required to successfully perform ultrasound guided procedures. This will increase efficiency, safety, quality, and reduce costs for ultrasound guided procedures such as central line placements and peripheral nerve blocks. Furthermore, with the advent of highly portable ultrasound imaging systems, the needle guide will enable these procedures to be more easily performed by unskilled practitioners in non-ideal situations such as in the battlefield and at other disaster relief areas.

We plan to further enhance our mechanical design based on the feedback received from the clinical tests. To further validate the accuracy of our system, we plan to evaluate our system on mannequins with a subject group performing a more complex task, such as a central line placement. Time of procedure and the number of insertion attempts will be evaluated and compared between the two categories.

Acknowledgments

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